

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK**

ONY, INC.,

Plaintiff,

- vs -

Case No. 1:11-cv-01027-WMS

**CORNERSTONE THERAPEUTICS, INC.,
CHIESI FARMACEUTICI S.p.A.,
NATURE AMERICA, INC.,
d/b/a Nature Publishing Group,
EDWARD E. LAWSON, M.D.,
AMERICAN ACADEMY OF PEDIATRICS,
PREMIER, INC., d/b/a Premier Research Services,
RANGASAMY RAMANATHAN, M.D.,
JATINDER J. BHATIA, M.D.,
FRANK R. ERNST, Pharm.D. and
KRISHNAMURTHY C. SEKAR, M.D.,**

Defendants.

**REPLY MEMORANDUM OF LAW
IN SUPPORT OF PLAINTIFF'S MOTION
FOR EXPEDITED DISCOVERY**

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INTRODUCTION

This memorandum of law is submitted by plaintiff ONY, Inc. ("ONY") in reply to (1) the Opposition to ONY, Inc.'s Motion for Expedited Discovery by Defendants Cornerstone, Chiesi, Ramanathan, Bhatia and Sekar (the "Cornerstone Opposition") (Docket #42), (2) the Media Defendants' Memorandum of Law in Opposition to Plaintiff's Motion for Expedited Discovery (the "Nature Opposition") (Docket #31), (3) Defendant American Academy of Pediatrics' Response to Motion for Expedited Discovery (the "AAP Opposition") (Docket #40), (4) Defendants Premier, Inc. and Frank R. Ernst's Memorandum of Law in Opposition to Plaintiff's Motion for Expedited Discovery (the "Premier Opposition") (Docket #33), and otherwise in support of ONY's motion for expedited discovery. For the reasons that follow, that motion should be granted.

PRELIMINARY STATEMENT

This case is about commercial, not free, speech. The latter is protected by the First Amendment; the former is not, but rather is unquestionably subject to limitations imposed by the Lanham Act, FDA regulations regarding pharmaceutical advertising, and unfair trade practices acts.

That ultimate issue in the case, however, is not what this motion is about – notwithstanding the defendants' efforts to so make it. Rather, this motion is about whether ONY has demonstrated sufficient cause to be allowed discovery sooner rather than later. As shown below, it plainly has.

**ONY HAS SHOWN SUFFICIENT CAUSE FOR
EXPEDITED DISCOVERY TO BE ALLOWED**

This Court has rejected a preliminary injunction-like standard for granting expedited discovery in favor of a "good cause" or "reasonableness" standard. *United States v. Erie County*, 09-cv-849S (W.D.N.Y. 2010) (Docket #42) at 7 n.5 and accompanying text. This prevailing standard "provides more flexibility for the court to order expedited discovery." *Id.* (citations omitted). Regardless of the standard employed, however, ONY readily meets it.

I. The Relative Prejudice to the Parties Favors Allowing Expedited Discovery.

The defendants all recognize that a relevant consideration on ONY's motion is the comparative prejudice to the defendants if expedited discovery is allowed and to the plaintiff if it is denied. While the defendants all claim that they will be more prejudiced if discovery is allowed than ONY will be if it is not, they fail to acknowledge the cases cited by this Court which have "found that where an expedited discovery request is made in contemplation of the filing of a motion for preliminary injunction, the denial of that request prejudices the moving party." *Id.* at 7 (citing *OMG Fidelity, Inc. v. Sirius Technologies, Inc.*, 239 F.R.D. 300 (N.D.N.Y. 2006), and *Standard Investment Chartered, Inc. v. NASD, Inc.*, 2007 WL 1121734 (S.D.N.Y.)). Such is precisely the case at bar.

As an initial matter, it does not aid the defendants to argue (as they do) that ONY's inability to move for a preliminary injunction with the evidence it has presently in hand militates against allowing expedited discovery in aid of such a motion. Setting aside the circularity of such reasoning, not to mention this Court's seeming rejection of that logic in *United States v. Erie County*, *supra*, if ONY **had** moved for a preliminary injunction, the defendants most assuredly would be taking it to task for not having presented **enough** supporting evidence. ONY was not about to make a motion it could not support.

Next, the limited discovery sought by ONY (the narrowly-tailored scope of which is discussed below) is uniquely within the possession of the defendants. None of the defendants dispute that evidence of Cornerstone and Chiesi's post-publication dissemination of the Article is peculiarly within those defendants' possession. Moreover, evidence of the extent of Chiesi's "sponsorship" of the Article obviously does not reside with ONY; rather, such evidence is likely to reside with **any** of the defendants, to the **exclusion** of ONY. As discussed below, all such evidence is relevant to a preliminary injunction inquiry.

Nonetheless, defendants seek to defeat a preliminary injunction motion not on the merits **but by preventing it from being brought in the first place**, by arguing that ONY must definitively show "irreparable harm" as a **prerequisite to obtaining discovery in aid of** such a motion. However, rather than argue that the **type** of harm expected to be shown by ONY (diminished product value and indeterminate lost sales) is not redressable by money damages (as would be in dispute on a preliminary injunction motion), the defendants principally contend, for example, that "any claim of irreparable harm – or need for expedited discovery – by ONY is particularly meritless given that ONY delayed more than three months in bringing this lawsuit." Nature Opposition at 11. That argument, however, is both factually inaccurate and legally unsupported.

As for the facts, the accompanying declaration of ONY's president Edmund A. Egan, M.D. (the "Egan Declaration") lays out in abundant detail how diligent ONY has been in asserting its rights every step of the way – including not once but twice demanding the retraction which would have rendered this entire lawsuit unnecessary, and its prompt commencement of this action once it became apparent that such a retraction would not be immediately forthcoming. Unlike cases cited by the defendants such as *Comic Strip, Inc. v. Fox Television Stations, Inc.*,

710 F. Supp. 976, 981 (S.D.N.Y. 1989), where there was a "three month delay since the plaintiffs' last communication with the defendant" (Cornerstone Opposition at 12), here barely a month lapsed between when ONY demanded a retraction for the second time and when it commenced suit. Egan Declaration ¶¶ 6-8. Quite simply, "[t]his is not conduct which undercuts a sense of urgency or of an imminent threat." *King v. Innovation Books*, 976 F.2d 824, 831 (2d Cir. 1992).

Moreover, hospitals' purchasing decisions do not occur overnight, but rather any changes in pharmaceuticals take time to play out. Egan Declaration ¶ 5. This means both that there is a time lag between any misleading promotional use of the Article and any resultant decision to switch from Infasurf®, and also that ONY may not immediately learn about it when it did.

The three month "delay" which the defendants invoke as disabling ONY from obtaining expedited discovery (and a preliminary injunction along with it) pales in comparison to much longer periods of time which the Second Circuit and district courts within it have found insufficient to defeat a preliminary injunction motion. *See, e.g., King, supra*, 976 F.2d at 831 (eight-month lapse did not rebut presumption of irreparable injury where objections had been made and evidence requested); *Kuklachev v. Gelfman*, 361 Fed. Appx. 161, 163 (2d Cir. 2009) (eighteen month delay explainable, in part, by need to investigate nature of infringing conduct and to explore available legal recourse, and by absence of immediate threat of scheduled repetition of infringement); *Clifford Ross Co., Ltd. v. Nelvana, Limited*, 710 F. Supp. 517, 521 (S.D.N.Y. 1989), *aff'd without op.*, 883 F.2d 1022 (2d Cir. 1989) (seven-month delay explainable where plaintiff "was unaware of the true and pervasive extent of the violation of his contract rights" and "the intervening period ha[d] been consumed by constructive, responsible and accommodating efforts by plaintiff's legal counsel to resolve the matter without litigation.").

Here, as established in abundance by the Egan Declaration, between the time ONY learned of the publication of the Article in September 2011 and the time it brought suit in early December, it was unaware (and, in fact, still **is** unaware) of the full extent of Cornerstone and Chiesi's dissemination and other advertising use of the Article and was engaged in efforts to avoid litigation altogether. *See generally, Tom Doherty Associates, Inc. v. Saban Entertainment, Inc.*, 60 F.3d 27, 39 (2d Cir. 1995). As recognized in *Playboy Enterprises, Inc. v. Chuckleberry Publishing, Inc.*, 486 F. Supp. 414, 435 (S.D.N.Y. 1980), "[p]arties should not be encouraged to sue before a practical need to do so has been clearly demonstrated."

Taken as a whole, and while at least paying lip service to the applicable "good cause" or "reasonableness" standard, defendants' arguments in effect seek to hold ONY to a preliminary injunction standard as a prerequisite to ONY obtaining discovery in aid of a preliminary injunction. However, "employing a preliminary-injunction type analysis to determine entitlement to expedited discovery makes little sense, **especially when applied to a request to expedite discovery in order to prepare for a preliminary injunction hearing.**" *Ayyash v. Bank Al-Madina*, 233 F.R.D. 325, 326-27 (S.D.N.Y. 2005) (emphasis added). *See also, OMG, supra*, 239 F.R.D. at 305 ("[P]articularly given that plaintiff contemplates a motion for a preliminary injunction, depending upon the results of its proposed discovery efforts, it is clear that plaintiff will potentially be unfairly prejudiced should I not permit discovery to go forward since it will not have an early opportunity to develop evidence for use in support of such a motion.").

Even if held to a preliminary injunction standard, however, ONY has abundantly established its irreparable harm. Indeed, where, as here, false advertising compares specific competing products, "irreparable harm is presumed." *McNeilab, Inc. v. American Home*

Products Corp., 848 F.2d 34, 38 (2d Cir. 1988). This is because "a false 'comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer.'" *Time Warner Cable, Inc. v. DirectTV, Inc.*, 497 F.3d 144, 162 (2d Cir. 2007). Such is exactly the situation here.

II. The Discovery Sought Is Narrowly Tailored and Will Be Required in All Events.

Each of the defendants asserts that the requested discovery is overbroad, not narrow, and will not be necessary if their pending Rule 12(b)(6) motions are granted. Again, defendants are wrong.

The requested discovery does not "relate to all of the issues raised in the lawsuit." Cornerstone Opposition at 3. As Nature, Premier and the AAP recognize, only a limited number of the requests are even directed at them. Nature Opposition at 2, 5; Premier Opposition at 2, 3; AAP Opposition at 1. A variety of issues as to them go unexplored by ONY's proposed requests, such as the AAP's sponsorship of the Journal, its circulation, Premier's collection of data and the operation of its database, etc.¹ Even as to the remaining defendants, ONY's proposed requests leave a host of relevant issues untouched – chief among them Chiesi/Cornerstone's sales of Curosurf®, other research they may have done or sponsored, their generalized comparative marketing strategy, and the 2007 presentations. On all of those issues (and more), ONY awaits ordinary discovery.

Rather, ONY now seeks discovery related to but two issues: (1) "the extent to which Cornerstone and Chiesi have utilized the Article for promotional purposes, including the identities of hospitals, prescribing physicians, and other customers, potential customers or decisionmakers to whom Cornerstone and Chiesi have distributed the Article or publicized its

¹ ONY has not yet requested the "underlying data," as asserted by the Cornerstone Opposition at page 8.

contents"; and (2) "the funding or other sponsorship of the Article or its underlying 'study' by Cornerstone and Chiesi, including payments made by either of them to any of their co-defendants or others." Declaration of Mitchell J. Banas, Jr. (Docket #6) at ¶ 12. Plainly, these issues are directly related to the issues on ONY's anticipated preliminary injunction motion.

While Cornerstone/Chiesi, for example, claim that the "extent" of their commercial distribution of the Article to date "is not relevant to whether preliminary injunctive relief would be merited" and that instead "[o]nly contemplated future distributions are" (Cornerstone Opposition at 8), clearly their past distribution of the Article is relevant: Whether any such distribution was non-existent, or unauthorized, or tolerated, or coordinated, or concerted, or scripted (the permutations are virtually endless) and exactly how it was done all affect the preliminary injunction landscape. The discovery sought goes to that very issue.

Similarly, and unless the defendants are willing to dispense with the requirement altogether, on a preliminary injunction motion ONY would need to establish some level of likelihood of success on the merits² in order to enjoin Cornerstone and Chiesi's continued dissemination of the Article.³ While Chiesi's Lanham Act liability for **disseminating** the false Article is rather self-evident, its independent liability for **authoring** the Article so as to preordain its results (as the Complaint also alleges) is not. Such authorship, however, would present an independent basis for Lanham Act liability as against Chiesi. *See, e.g., Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 111-14 (6th Cir. 1995) (also discussing why the Lanham Act may permissibly prohibit false or misleading commercial speech without running afoul of the First Amendment).

² That the requested discovery goes to the "very issues raised by the Complaint" (Cornerstone Opposition at 9) is hardly surprising, since likelihood of success on the merits is a prerequisite to the issuance of a preliminary injunction.

³ While the defendants claim a certain lack of specificity as to the nature of the preliminary injunction motion to be sought by ONY, they all seem to have figured it out.

Given the Complaint's very specifically-alleged collusion between and among the defendants,⁴ **any** of them could conceivably have documents relative to that issue.

And if they don't, they don't. If Cornerstone and Chiesi did nothing more than passively "sponsor" the study, and had no involvement in its conduct, the evaluation of the underlying data, or the formulation of the study "results," there will be minimal if any responsive documents and no burden whatsoever on the defendants to produce anything. If, on the other hand, Cornerstone and Chiesi **were** active in shaping the study, documents identifying such participation are properly discoverable (regardless of any unquantified burden) and will provide some of the evidence on which to request a preliminary injunction.

Given the plain relevance of the requested discovery to preliminary injunction issues, cases cited by the defendants such as *St. Louis Group, Inc. v. Metals & Additives Corp.*, 275 F.R.D. 236 (S.D. Tex. 2011) (*see, e.g.*, Cornerstone Opposition at 12) are inapposite. ONY does not seek expedition on the grounds of speedy resolution "alone" (*St. Louis Group, supra*, 275 F.R.D. at 242), but rather because of the irreparable harm it will suffer if expedited discovery is not granted. That the discovery will be required in all events is simply offered as a reason why the defendants will not be prejudiced if discovery is permitted to proceed. *See, e.g., OMG, supra*, 239 F.R.D. at 305 (allowing expedited discovery in aid of preliminary injunction motion in part because "the discovery sought will in all likelihood occur eventually.").

Nor can the defendants legitimately avoid expedited discovery by arguing that the granting of their pending dismissal motions would render the requested discovery "unnecessary." Of course, the mere making of a dismissal motion effects no generalized stay of discovery (*see, e.g., id.* at 304) and, indeed, the defendants have not even moved for such a stay in connection

⁴ That Chiesi, Cornerstone and the Article's authors are represented by the same counsel certainly does nothing to disabuse the complaint's allegations of collusion.

with their motions. As will be shown in ONY's papers in opposition to those motions, those motions should be denied. Even being charitable, however, and positing that only the claims against Cornerstone and Chiesi survive (they clearly will), the other defendants – even if dismissed – would remain subject to discovery as non-parties. Accordingly, the pendency of the dismissal motions does not weigh in favor of the defendants either. *See, e.g., id.* at 305 (allowing expedited discovery in aid of preliminary injunction motion notwithstanding pendency of dismissal motions).

The defendants, of course, know full well that the linking of ONY's expedited discovery motion to the outcome of their own dismissal motions is likely to, at the very least, delay ONY's ability to obtain discovery (if only by virtue of the greater complexity of those motions and the concomitant additional deliberation they will require). *See, e.g.,* Cornerstone Opposition at 13 ("In the event that any of ONY's claims survive the motions to dismiss, discovery can be addressed at that time."). As demonstrated by the Egan Declaration, however, such delay only benefits the defendants, further demonstrating why the denial of discovery works more to the prejudice of the plaintiff than its permission does to the defendants.

III. Defendants' Demand-Specific Objections Are No Impediment to Expedited Discovery.

Defendants raise a number of specific objections to particular discovery demands as reasons why expedited discovery should not be allowed; those objections are red herrings. For example, Chiesi claims that its 30(b)(6) witness must be deposed in Italy rather than as noticed at the headquarters of its U.S. subsidiary (Cornerstone Opposition at 10); that may or may not be the case, but in all events this would be the subject of discussion and resolution in the ordinary course. Similarly, defendant Premier's objection that "[t]he time and cost associated with such a document review and production would be substantial" (Premier Opposition at 3) is an

inadequate basis on which to deny ONY's motion, since that purported "burden" is wholly unquantified, unsubstantiated, and conjectural – or, if real, would (again) typically be the subject of compromise and accommodation. Likewise with respect to Nature's objection that the "lone request" to it impermissibly includes within its scope "peer review" documents it claims are "confidential" (Nature Opposition at 9); any such objection to a **portion** of a request can be taken up in the ordinary course. Certainly, such request-specific technical objections are not a proper basis on which to prevent discovery from even **beginning**. *See, e.g., OMG, supra* (allowing expedited discovery in aid of preliminary injunction motion to go forward over overbreadth objection as to one request where plaintiff's counsel demonstrated willingness to limit the request, but declining to shorten defendants' time within which to respond).

CONCLUSION

For the foregoing reasons, and the reasons set forth in the Egan Declaration and ONY's moving papers, ONY's motion for expedited discovery should be granted.

DATED: Buffalo, New York
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